ORIGINAL ARTICLES

Drug Complications in Outpatients

Tejal K. Gandhi, MD, MPH, Helen R. Burstin, MD, MPH, E. Francis Cook, ScD, Ann L. Puopolo, BSN, RN, Jennifer S. Haas, MD, MSPH, Troyen A. Brennan, MD, JD, MPH, David W. Bates, MD, MSc

OBJECTIVE: **Outpatient drug complications have not been well studied. We sought to assess the incidence and characteristics of outpatient drug complications, identify their clinical and nonclinical correlates, and evaluate their impact on patient satisfaction.**

DESIGN: **Retrospective chart reviews and patient surveys.**

SETTING: **Eleven Boston-area ambulatory clinics.**

PATIENTS: **We randomly selected 2,248 outpatients, 20 to 75 years old.**

MEASUREMENTS AND MAIN RESULTS: **Among 2,248 patients reporting prescription drug use, 394 (18%) reported a drug complication. In contrast, chart review revealed an adverse drug event in only 64 patients (3%). In univariate analyses, significant correlates of patient-reported drug complications were number of medical problems, number of medications, renal disease, failure to explain side effects before treatment, lower medication compliance, and primary language other than English or Spanish. In multivariate analysis, independent correlates were number of medical problems (odds ratio [OR] 1.17; 95% confidence interval [95% CI] 1.05 to 1.30), failure to explain side effects (OR 1.65; 95% CI, 1.16 to 2.35), and primary language other than English or Spanish (OR 1.40; 95% CI, 1.01 to 1.95). Patient satisfaction was lower among patients who reported drug complications ($P < .0001$). In addition, 48% of those reporting drug complications sought medical attention and 49% experienced worry or discomfort. On chart review, 3 (5%) of the patients with an adverse drug event required hospitalization and 8 (13%) had a documented previous reaction to the causative drug.**

CONCLUSIONS: **Drug complications in the ambulatory setting were common, although most were not documented in the medical record. These complications increased use of the medical system and correlated with dissatisfaction with care. Our results indicate a need for better communication about potential side effects of medications, especially for patients with multiple medical problems.**

KEY WORDS: **adverse drug events; ambulatory care; patient satisfaction; quality of care; drug complication.**
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Received from the Division of General Medicine, Brigham and Women's Hospital, Boston, Mass (TKG, HRB, EFC, ALP, TAB, DWB), and Division of General Internal Medicine, San Francisco General Hospital, University of California, San Francisco, Calif (JSH).

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Address correspondence and reprint requests to Dr. Bates: Chief, Division of General Medicine, Brigham and Women's Hospital, PBB-A3, 75 Francis St., Boston, MA 02115 (E-mail: dwbates@bics.bwh.harvard.edu).

Therapeutic drugs are a core component of the practice of medicine; 75% of office visits to primary care providers involve the initiation or continuation of drug therapy.[1] Adverse drug events (ADEs), defined as injuries due to drugs, occur commonly in the hospital setting. In the ADE Prevention Study, ADEs occurred at a rate of 6.5 per 100 admissions, and 28% of these events were preventable.[2] Many other studies have also been done to characterize inpatient ADEs.[3–6]

Data suggest that ADEs among outpatients are an important problem as well. A recent meta-analysis suggested that in 1994 more than 1 million outpatients in the United States experienced an ADE that required admission to the hospital, and that 4.7% of admissions were caused by drugs.[7] The study also suggested that there were 106,000 fatal ADEs in the United States in 1994, which would place them between the fourth and sixth leading causes of death, although these projections may be high.[8] A recent study of U.S. death certificates showed that the number of people who reportedly died from medication errors increased by 2.5-fold from 1983 to 1993,[9] suggesting that the problem may be worsening. However, compared with the inpatient setting, there is relatively little information about ADEs in the ambulatory setting. Estimates of the proportion of outpatients experiencing an ADE per year have ranged from 5% to 35%.[10,11]

Several reasons exist for the relative lack of information about ADEs in the ambulatory setting. In contrast to inpatients, outpatients are responsible for both obtaining and administering their medications. Therefore, the process is much less controlled. Also, physicians have less regular contact with outpatients and are less likely to hear about their problems. Chart review also has limitations related to high costs and inadequate documentation.[12] Therefore, previous studies of outpatients have relied heavily on patient report, which has inherent limitations. Dependence on patients' recall during interviews or on re-

sponses to questionnaires substantially limits assessments of the risk of drug therapy.[13] The standard definition of an ADE that was used in inpatient studies cannot be used in the setting of patient-reported side effects since these side effects often cannot be verified as drug-related. For our purposes, we will define patient-reported events as drug complications, rather than ADEs.

To better assess the frequency, preventability, and consequences of outpatient drug complications, we performed a study with the following goals: to compare chart review with patient survey for identification of these complications; to describe drug complications that occur in outpatients; to identify clinical and nonclinical correlates of outpatient drug complications and thus determine potentially modifiable factors; and to evaluate the relations among outpatient drug complications, their consequences (such as the need for additional care), and patient satisfaction with care.

METHODS

Study Setting

The Ambulatory Medicine Quality Improvement Project was designed to examine factors associated with variation in the quality of care at 11 general internal medicine practices associated with Harvard Medical School teaching hospitals. All of these sites are located in the Greater Boston area, but they are diverse in location, structure, and degree of academic affiliation. The sites included 6 hospital-based practices, a university health service with a group-model HMO structure, a large commercial group-model HMO, 2 neighborhood health centers in low-income communities, and a suburban group practice. The study was approved by the Institutional Review Board of each institution.

Patient Selection

Patients were randomly selected for this study if they were between the ages of 20 and 75 years and had made at least one visit to an attending-level primary care physician during the preceding year. Six hundred patients meeting these eligibility criteria were selected randomly from each site. Eligible patients were sent informational letters about the study and asked to return an "opt-out" postcard if they did not want to participate. The medical records of patients who did not opt-out were reviewed by trained research nurses, up to a maximum of 500 participants per site. Attempts were then made to contact these patients by telephone to complete a telephone survey. Patients were eligible for the survey if they spoke English or Spanish and excluded if they were hard of hearing, too ill, had an inaccurate telephone number, or had died prior to the survey.

Survey Design

The telephone survey included questions about sociodemographic characteristics, patient satisfaction with medical care, health status, health care utilization, and drug complications within the past year. Patients were asked to rate several aspects of their health care using questions derived from the Medical Outcomes Study.[14] Questions about drug complications were derived from previous outpatient surveys.[10,15] Surveys consisted of approximately 120 questions and lasted 30 minutes.

Data Collection

Medical record reviews were completed by research nurses for all patients in the final sample from May 1996 to June 1997. A medical record abstraction form was used to collect information on diagnoses, medications, allergies, hospitalizations, and ADEs within the past year. After medical record review, patients were contacted to complete the telephone survey. All patient surveys were conducted between August 1996 and October 1997. Chart review and survey data were linked by the patient's unique study identification number, and only patients with both chart review and survey data were used in the final analysis (N = 2,858).

Main Outcome Measures

In the patient survey, patient-reported drug complications, defined as a problem or symptom related to their prescription medications in the past year, were the main outcome of interest. As a validity check, complications were verified to be documented drug-symptom associations by a physician reviewer using the *Physicians' Desk Reference (PDR)*.[16]

On chart review, the outcome of interest was ADEs, as noted by registered nurses, verified by a physician, and classified as possible, probable, or definite according to Naranjo criteria.[17] In addition, the physician characterized the severity of the ADE (significant, serious, life-threatening, or fatal) using previously published criteria.[2] As examples, a significant ADE would be a drug rash, a serious ADE would be diarrhea requiring intravenous hydration, and a life-threatening ADE would be a cerebral hemorrhage.

Another outcome variable was overall patient satisfaction with care, which was based on patient ratings, using Likert-scale satisfaction questions from the ambulatory Picker survey (The Picker Institute, Boston, Mass). An overall satisfaction score was created from a combination of four satisfaction questions: How satisfied are you with your health care provider? (scale 1–5), How satisfied are you with the overall quality of the practice? (scale 1–5), Would you recommend the practice to your family or friends? (yes or no), and Do you plan to come back to the practice? (yes or no). Patients with more than two missing values were excluded. Scores were on a scale of 50 to 100, with 100 being the highest.

Other covariates collected on patient survey included patient age, sex, race, level of education (categorized as

less than high school, high school graduate, college graduate, or postgraduate degree), language (categorized as English, Spanish, or other), and insurance status (categorized as insured or uninsured).

Analysis

Data on drug complications based on self-report and chart review data were collected separately. Univariate analyses of discrete data and nonnormal continuous data were conducted using χ^2 and Wilcoxon rank sum tests, respectively. Logistic regression using a backward elimination algorithm was used for multivariate analysis of reported drug complications (cutoff of $P \leq .05$); only those variables significant on univariate analysis ($P \leq .05$) were included. Continuous variables were tested for the assumption of linearity. Multivariate analysis of patient satisfaction scores was performed with linear regression. All analyses were done using SAS software (SAS Institute, Cary, NC).

RESULTS

Detection of Events

Chart review data and matching survey data were obtained on 2,858 (69%) of 4,167 eligible individuals. Prescription drug use was reported by 2,248 (79%) of 2,858 patients. Of the patients taking prescription drugs, 394 (18%) reported having had a drug complication, defined as a problem or symptom in the last year related to their prescription medications. Patients who reported problems were similar to patients who did not in terms of age, gender, race, education level, and insurance status (Table 1).

On chart review, evidence of an ADE was found in only 64 (3%) of 2,248 patients. All 64 events were verified as ADEs using the Naranjo technique[17] (1 was possible, 62 were probable, and 1 was definite). In addition, the severity of the ADEs was assessed: 1 was life-threatening, 7 were serious, and the remaining 56 were significant.

Of the 432 events detected by at least one method, 26 (6%) were detected by both patient survey and chart review (Table 2); the patient survey identified 91% of events and chart review identified 15%. Chart review was more likely to produce evidence of an ADE if the medical record was computerized ($P = .03$). Patients whose events were detected by both methods were more likely to have sought medical attention than patients whose events were detected by survey alone ($P = .03$). Events detected by both methods did not differ in severity compared with events detected by chart review alone.

Description of Drug Complications

Patients were able to name the actual drug involved in 199 (51%) of 394 drug complications. Of these, 153 (77%) of 199 were verified as documented drug-symptom associations in the *PDR* (see "Methods" section). Among those not verified, 22 had a stated symptom that was not in the *PDR* and 24 reported a symptom that was in the "other" category and therefore could not be verified.

Patients reported that the drugs most commonly involved were antibiotics (21%), antidepressants (13%), and nonsteroidal anti-inflammatory agents (6%). The most frequently reported side effects were gastrointestinal symptoms, sleep disturbances, fatigue, and mood changes (Table 3). Gastrointestinal symptoms were most commonly described as the worst side effect (25% of patients surveyed).

In the chart review, the types of ADEs that were found and judged to be the worst complication were allergic reactions/rashes (36% of the 64 ADEs), gastrointestinal (14% of ADEs), central nervous system (11%), metabolic (5%), cardiovascular (3%), bleeding (2%), and other (30%).

Preventability of Drug Complications

In 8 (13%) of the 64 identified ADEs, patients had previously had a documented allergic or other reaction to

Table 1. Patient Characteristics*

Characteristics	Patients Reporting a Drug Complication (n = 394)	Patients Not Reporting a Drug Complication (n = 1,854)
Mean age, y	44.6	46.1
Male gender, *n* (%)	125 (32)	644 (35)
Race, *n* (%)		
White	290 (74)	1,403 (76)
African-American	54 (14)	212 (11)
Asian	9 (2)	42 (2)
Latino/Hispanic	42 (11)	170 (9)
Education, *n* (%)		
<12th grade	21 (5)	116 (6)
High school graduate	145 (37)	699 (38)
College graduate	113 (29)	518 (28)
Postgraduate degree	109 (28)	488 (26)
Primary language, *n* (%)†		
English	357 (91)	1,644 (90)
Spanish	17 (4)	122 (7)
Other	19 (5)	51 (3)
Insurance status, *n* (%)		
Insured	369 (94)	1,763 (95)
Uninsured	20 (5)	78 (4)

**Some percentages do not add up to 100 because of rounding.*
†$P < .05$ by χ^2 analysis of difference between the 2 groups.

Table 2. Adverse Drug Event (ADE) Detection by Method

	ADE Found on Patient Survey	
ADE Found on Chart Review	No	Yes
No	1,816	368
Yes	38	26

Table 3. The Most Frequent Patient-Reported Drug Complications Among Patients Taking Prescription Drugs (N = 2,248)

Side Effect	*n* (%)
Gastrointestinal	158 (7)
Sleep disturbances	112 (5)
Fatigue	99 (4)
Mood changes	97 (4)
Disequilibrium	89 (4)
Headache	86 (4)
Rash	67 (3)
Musculoskeletal	67 (3)
Incontinence	36 (2)

the causative drug. Five events involved a drug that required blood-level monitoring. Among patients reporting a drug complication (n = 394), 13% thought that the event could have been prevented. In addition, 35% reported that their medication had not been changed after the problem occurred, and 20% reported symptoms lasting longer than 3 months.

Clinical Correlates of Complications

In univariate analyses, significant clinical correlates of patient-reported events were number of medical problems, number of medications, and renal disease (all $P <$ .05). Significant nonclinical correlates were failure to have side effects explained before treatment, lower medication compliance, and a primary language other than English or Spanish (all $P <$ .05) (Table 4). There was no relation between race, gender, age, or education and reported side effects. Multiple logistic regression showed that independent correlates of patient-reported drug complications were number of medical problems (odds ratio [OR] 1.17; 95% confidence interval [95% CI] 1.05 to 1.30), failure to have side effects explained before treatment (OR 1.65; 95% CI, 1.16 to 2.35), and a primary language other than English or Spanish (OR 1.40; 95% CI, 1.01 to 1.95) (Table 4).

Patient Satisfaction

A summary measure of overall patient satisfaction with care was created (see "Methods" section). The level of overall satisfaction was significantly lower among patients who reported problems related to medication use than among those who did not (93.7 vs 96.8, $P <$ .0001) (Table 5). This effect persisted in multivariate analysis after adjustment for age, gender, race, and clinic site. In patients who experienced a drug complication, significantly lower overall satisfaction scores were found for those who thought their event could have been prevented, whose physician did not explain the specific side effect before treatment, and whose symptoms had been present longer than 3 months (Table 5).

Impact of Complications

By patient survey, 193 (49%) of the 394 patients who reported a drug-related problem experienced worry or discomfort, 190 (48%) sought medical attention, and 136 (35%) reported interference with work, leisure, or activities of daily living. On chart review, 3 of the 64 patients with an ADE were found to have required hospitalization.

DISCUSSION

Drug complications occurred commonly in the ambulatory setting, particularly when based on patient report. However, most were not noted in the medical chart, and there was little overlap between events detected using patient survey and chart review. These complications generally represented valid drug-symptom associations, often lasted for long periods of time, and had important consequences. For instance, patients who reported drug complications were less satisfied with their care, experienced morbidity in terms of both symptoms and interference with activities of daily living, and required additional use of the health care system. Also, we found several clinical

Table 4. Correlates of Patient-Reported Drug Complications

Correlate	Patient-Reported Drug Complication?		Multivariate Odds Ratio (95% CI)*
	Yes	No	
Clinical correlates			
Average number of medical problems†	1.5	1.2	1.17 (1.05 to 1.30)
Average number of medications†	3.8	3.3	NS
Renal disease,† %	3.6	1.1	NS
Nonclinical correlates			
Failure to have side effects explained before treatment,† %	24	16.4	1.65 (1.16 to 2.35)
Primary language other than English or Spanish,† %	4.8	2.8	1.40 (1.01 to 1.95)
Reported medication noncompliance,† %	11	6	NS

**CI indicates confidence interval; NS, not significantly different from 1.*

†$P <$ .05 in univariate analysis of the difference between those with and without a patient-reported drug complication; age, gender, education, race, and clinic site were all nonsignificant.

Table 5. Relation of Overall Satisfaction to Patient-Reported Drug Complications*

Satisfaction Measure	Yes		No		*P* Value
	Number of Patients	Mean Satisfaction Score	Number of Patients	Mean Satisfaction Score	
Patient reported a drug complication	394	93.7	1,828	96.8	<.001†
Patient thought event was preventable	38	90.9	257	95.1	NS
Symptoms lasted longer than 3 mo	56	89.1	201	95.1	<.01
Side effect not explained before treatment	168	91.7	170	95.4	<.01

**Number of resondents varies per question due to nonrespondents.*
†*Adjusted for age, gender, race, and clinic site; NS indicates not significant (P > .05).*

and nonclinical correlates of drug complications, some of which may be amenable to intervention. In addition, some complications were clearly preventable, for example, those due to known drug allergies.

The 2 most likely reasons that chart review did not reveal as many events as patient survey are that patients do not report all such events to their physicians, and physicians fail to document them. Only 6% of events were found by both methods, and these events occurred in patients who were especially likely to seek medical attention. Different detection methods (voluntary report, chart review, and computer detection) have been shown to capture different events.[12,18] Events were more likely to be detected if the clinic had computerized medical records. This effect is most likely due to detection bias since, in comparison with paper charts, computerized records provide more legible, organized documentation for ADE detection. An extension of computerized records is the use of computer-based monitors to detect ADEs, several of which have been implemented in the hospital setting.[19,20] These monitors use computerized signals such as use of an antidote or abnormal laboratory tests, with confirmation by clinical follow-up, to detect ADEs.[18] Although this approach has been used primarily in inpatients, computer-based monitoring in the outpatient setting (as opposed to chart review or survey techniques) may be a practical and efficient approach for measuring ADE frequency and severity.[21]

Drug complications were associated with lower overall patient satisfaction with care. In addition, when patients perceived a potential quality issue, such as a preventable complication, longer symptom duration, or lack of discussion about side effects before treatment, they were more dissatisfied. In addition to reporting effects on patient satisfaction, patients reported substantial worry, discomfort, and interference with activities of daily living. Although less-satisfied patients may be more likely to report drug complications, it also may be true that the drug complications are contributing to these patients' dissatisfaction. The majority of the ADEs detected were classified as significant (not severe or life-threatening). Physicians often take these types of reactions for granted in the course of medical therapy. However, it is important to realize that these events are not minor to patients; physicians may underestimate the impact of these events on patient satisfaction, health care utilization, and quality of life.

We found several potential targets for preventive interventions. A small but important proportion of drug complications were clearly preventable. On chart review, 13% of events occurred in patients who had a documented prior allergic or other reaction to the causative drug. This is most likely an underestimate of the true proportion of events that are preventable. Information systems that include pretreatment allergy checks would almost certainly reduce the number of ADEs.[2] In addition, the drugs most commonly involved were antibiotics, which are often prescribed unnecessarily.[22] Examining prescribing practices could possibly reduce future complications. Clinical correlates of drug complications, such as number of medical problems, might be used to target high-risk groups. Finally, failure to explain side effects before treatment was associated with both increased reporting of drug complications and decreased patient satisfaction. Some clinicians may worry that telling patients about potential side effects increases the chances that they occur. These data do not directly address this issue, but they suggest that patients are less likely to report a complication and are more satisfied if the potential risks are explained in advance. Patients who know in advance about potential side effects may handle them better or have less concern about them. Therefore, improving patient education about side effects is a promising intervention that could reduce patient-reported drug complications.

This study has several limitations. Though patients may ascribe symptoms to a drug complication, we could not determine for certain if the symptoms were related to the drug in question. However, in an earlier survey of 1,026 outpatients over a 1-year period, suspected ADEs were subsequently classified as possible, probable, or definite in 86% of cases,[10] suggesting that most reported complications were valid. We addressed this issue by comparing patient-reported symptoms with reported drug symptoms in the *PDR*, with a verification rate of 77%. However, we had limited data to assess the timing of symptoms or improvement after drug discontinuation. Another limitation is that the event rate on chart review relies completely on provider documentation, which is often incomplete.[23] There is also potential for sampling bias

because patients with side effects may have been more likely to respond to the survey. To minimize this concern, the patient survey was designed to address many different health care issues and was not described to patients as relating to drug complications. Recall bias could also be an issue in that patients with side effects may think symptoms lasted longer than they did or may not remember being told about side effects beforehand. The appropriateness of medication prescribing was not assessed, and only patients, not physicians, were asked if the complications could have been prevented. In addition, the only measure of compliance was patient report, which is probably an overestimate. Finally, because the study was done in general medicine clinics, in an urban setting, affiliated with academic teaching centers, the results may not be generalizable to other sites.

We conclude that patient-reported drug complications are common in the outpatient setting and have important clinical consequences for patients. Patients report many more complications due to medications than are found in the medical record. Many of these drug complications may be preventable through computerized prescribing systems that can detect potential problems, such as allergies and drug-drug interactions. In addition, our data also suggest the need for better doctor-patient communication and education about drug therapy issues.

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